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Mr. V. Bhaskar
Joint Secretary
Department of Industrial Policy and Promotion (DIPP)
Ministry of Commerce and Industry
Room No. 236
Udyog Bhavan
New Delhi - 110 011

September 30, 2010

Dear Mr. Bhaskar,

Public Citizen submits the following comments regarding the DIPP discussion paper on compulsory licensing.

With 150,000 members and supporters, Public Citizen is a U.S.-based nonprofit consumer advocacy organization founded in 1971 to represent consumer interests. Key areas of organizational focus include public health, trade, competition policy, pharmaceutical drug safety and efficacy, and global access to medicines.

Public Citizen's Access to Medicines Program provides technical assistance to countries interested in using flexibilities in intellectual property rules to promote access to medicines. As noted in DIPP's discussion paper, Ecuador issued a compulsory license for the HIV/AIDS drug ritonavir in April of this year. Public Citizen has provided technical assistance to Ecuador throughout the development of its compulsory licensing protocol.

Public Citizen believes Ecuador's protocol offers a positive and concretely instructive example for countries interested in compulsory licensing. For your consideration and reference while weighing the *Issues for Resolution* described in DIPP's discussion paper, we include here a brief description of Ecuador's experience, and source documents detailing Ecuador's policy.

In October of 2009, Ecuador's President Rafael Correa issued Decree 118, declaring access to priority medicines affecting the health of the Ecuadorean population to be a matter of public interest. Decree 118 articulates basic procedures by which the Ministry of Public Health and patent office can cooperate to issue compulsory licenses for public

interests such as reducing treatment costs and enabling greater access to treatment. President Correa also created a public pharmaceutical firm, Enfarma, to help implement the decree and coordinate medicine purchases. Decree 118 followed public pronouncements by Correa articulating a vision of intellectual property as “a mechanism for development for the people.”

On April 14, 2010, Ecuador’s Intellectual Property Institute (IEPI) issued a compulsory license for the patented drug ritonavir, a key component in HIV/AIDS treatments. The license authorizes Eske Group, a Cipla affiliate, to sell ritonavir for use in Ecuador’s public programs, and employs the tiered royalty method (TRM) to determine adequate remuneration to patent holder Abbott Laboratories. The license and Ecuador’s licensing protocol comply fully with the World Trade Organizations’ Agreement on Trade-Related Aspects of Intellectual Property Rights (WTO’s TRIPS), and represent an important step toward ensuring access to medicines for all.

For more information, please see the following documents, attached and also available at the listed URLs:

- Resolution of the Ecuadorean Institute of Intellectual Property (IEPI) granting a compulsory license for ritonavir, April 14, 2010.
 - Official Spanish *available at*: http://www.citizen.org/documents/access_attachment_3.pdf.
 - Unofficial English translation *available at*: <http://www.citizen.org/documents/EcuadorCompulsoryLicenseTranslationUNOFFICIAL.pdf>.
- Decree 118 of President Rafael Correa, declaring access to priority medicines a matter of public interest, October 23, 2009.
 - Official Spanish *available at*: <http://www.sigob.gov.ec/decretos/>.
 - Unofficial English translation *available at*: <http://citizen.org/Page.aspx?pid=3247>.
- IEPI Resolution 10-04 (*Instructivo*), providing formal guidance to license applicants, January 15, 2010 (official Spanish).
- *Backgrounder*: Ecuador’s Presidential Declaration on Access to Medicines and Compulsory Licensing, Essential Action, October 26, 2009, *available at*: <http://www.essentialaction.org/access/index.php?/archives/226-Backgrounder-about-Ecuadors-Presidential-Declaration-on-Access-to-Medicines-and-Compulsory-Licensing.html>.
- Public Citizen comments to the Office of the United States Trade Representative (USTR), regarding the 2010 Special 301 review and Ecuador’s TRIPS-compliant licensing protocol, February 16, 2010.

Public Citizen will provide further documentation upon request. Public Citizen is also

we would be happy to

available to consult further regarding the *Issues for Resolution*, and regarding the use of compulsory licenses to improve global access to medicines.

Sincerely,

A handwritten signature in black ink, appearing to read "Peter Maybarduk". The signature is fluid and cursive, with the first name "Peter" being the most prominent.

Peter Maybarduk
Access to Medicines Program Director
pmaybarduk@citizen.org

